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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,569	10/26/2001	Esha A. Gangolli	21402-191 (CURA 491)	8659

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EXAMINER	
PAK, MICHAEL D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,569	GANGOLLI ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

A. Claims 1-4,29,32, drawn to an isolated polypeptide, classified in class 530, subclass 300.

B. Claims 5-14,30,33 drawn to isolated nucleic acids, vectors, and a host cell, classified in class 536, subclass 23.1.

C. Claims 15-17,31,34 drawn to an antibody against polypeptides of Group I, classified in class 530, subclass 387.1.

D. Claim 18, drawn to a method of screening a sample for the polypeptide of Group I, classified in class 435, subclass 7.1.

E. Claim 19, drawn to a method of screening a sample for a nucleic acid molecule, classified in class 435, subclass 6.

F. Claim 20, drawn to methods of identifying an agent that binds to the polypeptide of claim 1, classified in class 435, subclass 4.

G. Claim 21, drawn to a method of identifying an agent that modulates the expression or activity of the polypeptide of claim 1, classified in class 435, subclass 7.1.

H. Claim 22, drawn to a method of modulating activity of the polypeptide of Group I, classified in class 435, subclass 7.2.

I. Claims 23-24, 40, drawn to a method of treating a NOVX-associated disorder with a polypeptide, classified in class 514, subclass 12.

J. Claims 25,26, drawn to a method of treating a NOVX-associated disorder with nucleic acid, classified in class 514, subclass 44.

K. Claims 27, 28, 41, drawn to a method of treating a NOVX-associated disorder with antibody, classified in class 424, subclass 130.

L. Claim 35, in part, drawn to the use of a NOVX polypeptide in the manufacture of a medicament, classified in class 435, subclass 4.

M. Claim 35, in part, drawn to the use of a NOVX nucleic acid in the manufacture of a medicament, classified in class 436, subclass 6.

N. Claim 35, in part, drawn to the use of a NOVX antibody in the manufacture of a medicament, classified in class 435, subclass 4.

O. Claims 36, 37, drawn to method of screening a test compound in a transgenic animal, classification depends upon the structure of the compound.

P. Claim 38, drawn to method of measuring the level of expression of the polypeptide, classified in class 435, subclass 7.1.

Q. Claim 39, drawn to method of measuring the amount of nucleic acid, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons.

Groups A, B and C are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the polypeptide of Group A can be isolated from different sources, such as native cell lines or peptide syntheses. The DNA of group B can be used to make proteins and in other assays such as gene therapy or as a probe in hybridization assays. The antibodies of Group C are prepared by processes which are materially different from the process that prepares the DNA for Group B and polypeptide for Group A. Additionally, Group may be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods.

b. Although there are no provisions under the section for "Relationship of inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions D-Q are different methods because they require different ingredients, process steps, and end points. Groups D-Q are different methods where each is not required for one another. For example, Invention D requires search and consideration for screening of polypeptide by immunoassay or other peptide binding assays, which is not required by the other inventions. Invention E requires search and consideration for screening nucleic acid by hybridization or other quantitative methods, which is not required by the other inventions. Invention F requires search and consideration for identifying agent that binds to polypeptide, which is not required by the other inventions. Invention G requires search and consideration for methods of identifying agent that modulates activity of polypeptide of Invention A, which is not required by the other inventions. Invention H requires search and consideration of modulating activity of polypeptide of Invention A, which is not required by the other inventions. Invention I requires search and consideration of treating a NOVX-associated disorder with a polypeptide, which is not required by the other inventions. Invention J requires search and consideration of treating a NOVX-associated disorder with a nucleic acid, which is not required by the other inventions. Invention K requires search and consideration of treating a NOVX-associated disorder with an antibody, which is not required by the other inventions. Invention L requires search and consideration of using a polypeptide to manufacture medicament for treating a NOVX-associated disorder, which is not required by the other inventions. Invention M requires search and consideration of using a nucleic acid to manufacture medicament for treating a NOVX-associated disorder, which is not required by the other inventions. Invention N requires search and consideration of using an antibody to manufacture medicament for treating

a NOVX-associated disorder, which is not required by the other inventions. Invention O requires search and consideration for method of screening a test compound in transgenic animals, which is not required by the other inventions. Invention P requires search and consideration for method of screening protein levels in a mammalian subject and comparing with another group, which is not required by the other inventions. Invention Q requires search and consideration for method of screening nucleic acid levels in a mammalian subject and comparing with another group, which is not required by the other inventions.

c. Inventions A and D, F-I, L, O and P are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in materially different process such as in making antibody or in protein binding assays.

d. Inventions B and E, J, M and Q are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in materially different process such as in nucleic acid hybridization.

e. Inventions C and K, N are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in materially different process such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography).

f. Inventions A/ E, J, K, M and Q are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are unrelated product and use of product. For example, the claimed methods of Inventions E, J, K, M and Q do not recite the use or production of isolated polypeptide of Invention A.

g. Inventions B/D, F-I, K, L, N-P are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are unrelated product and use of product. For example, the claimed methods of Inventions D, F-I, K, L, N-P do not recite the use or production of isolated nucleic acids and vectors of Invention B.

h. Inventions C/D-J, L, M, O-Q are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are unrelated product and use of product. For example, the claimed methods of Inventions D-J, L, M, O-Q do not recite the use or production of an antibody of Invention C.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements and divergent subject matter, restriction for examination purposes as indicated is proper.

2. Restriction to one of the following inventions is also required under 35 U.S.C. 121:

Groups 1-17. The inventions as they pertain to each of SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, and /or 34 classification dependent upon the nature of the inventions. For example, if Applicant elects Group 2, the invention will be examined to the extent that it reads on SEQ ID NO: 4.

The inventions are distinct, each from the other because of the following reasons:

i. Although there are no provisions under the section for "Relationship of inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to

different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of the sequences in Groups: 1-17 is a unique amino acid sequence, requiring a unique search of the prior art. Searching all of the above sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their separate search requirements, restriction for examination purposes as indicated is proper.

3. Restriction to one of the following inventions is also required under 35 U.S.C. 121:

Groups 18-34. The inventions as they pertain to each of SEQ ID NOS: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, and/or 33 classification dependent upon the nature of the inventions. For example, if Applicant elects Group 19, the invention will be examined to the extent that it reads on SEQ ID NO: 3.

The inventions are distinct, each from the other because of the following reasons:

j. Although there are no provisions under the section for "Relationship of inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of the sequences in

Groups: 18-34 is a unique nucleic acid sequence, requiring a unique search of the prior art. Searching all of the above sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their separate search requirements, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must select on from Group A-Q, one from Group 1-17, and one from Group 18-34. Applicant is advised that neither A-Q, 1-17 nor 18-34 are species election requirements; rather each of A-Q, 1-17 and 18-34 is a restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is (571) 272-0879. The examiner can normally be reached on Monday through Friday, 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

Gyan Chandra
Art Unit 1646
24 June 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER